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Specialty Services for Life Science Clients

Interview with: *Dan Renick -* *Co-President and Chief Commercial Officer,* **Precision for Medicine**

CEOCFO: *Mr. Renick, your site indicates the tagline "The Future of Medicine Is Precision." How so?*
Mr. Renick: We feel—and of course the market largely feels this way as well—that the focus is shifting away from the treatment of large populations for conditions that have been the focus for a number of years: cholesterol reduction, blood pressure control, diabetes control, and so on. We have a number of good therapies that are on the market and more still to come. And there are still unmet needs in those therapeutic areas. However, both for those unmet needs as well as more specialized needs in a range of oncology and specialty conditions—including rare and orphan disease states—there is much more targeting of individuals based on the fact that we have the technology to do that now. Therefore, through biomarkers and other genomic capabilities, we can now have research and development throughput that is much more focused than it has been in the past. It allows us to address a number of unmet needs with true medical breakthroughs.

CEOCFO: *Where does Precision for Medicine come in? How do you play a part?*
Mr. Renick: There are two ways that Precision for Medicine plays a part. We have one portion of the company that is very focused on supporting the early research effort that focuses on the use of biomarkers within clinical trials to be able to target patients in a more personalized and precise manner. Therefore, through that and through the stratification of high-risk patient groups, we can improve the efficiency or we can support our clients to improve the efficiency of the research and development process. We see numerous news reports about how expensive it is and how long it takes to get a drug to market. Through these collective efforts, the industry at large wants to shorten that, so that a patient who has an unmet need can perhaps be the beneficiary of a medical breakthrough sooner. However, that is only part of the equation. The other part is how we can assign value to these medical breakthroughs and determine how we are going to pay for them; not only how much we will pay, but how we might go about paying for these things in the future. This has certainly been a hot topic with medical breakthroughs within the hepatitis C therapeutic area. There is lots of debate about the cost of these products. Much of that is centered on when the value will actually be received versus when the payment is made, because at least here in the US, the payment is largely all made up front, where the benefits may be received over a number of years. Therefore, just bringing medical breakthroughs to market is one aspect of this. The other is ascribing value and to whom that value will benefit.

CEOCFO: *Are you working with clients beginning to end in developing a strategy?*
Mr. Renick: That is a great question on how we can and do work with clients, and you will perhaps hear phrases like "molecule to medicine cabinet" or "bench to bedside." Ideally, we will be in that situation, and with emerging growth clients, that is starting to be the case, where we will be engaged very, very early in the research effort with the entire lifecycle of the product in mind. That is, what types of registrational trials are going to be developed and executed? Within those trials, what kind of evidence will be developed that can justify and support the value of the product, and ultimately, how does that product then get into the marketplace and reach the appropriate patient population that it is designed for? How that plays out with our clients will to some degree vary on the client's size, given how very large pharmaceutical clients will tend to be segmented in such a way that some bridge-building is required. Part of our mission is to support our clients as they internally look to make sure that those bridges are built. As I said, our R&D efforts are considering eventual commercial efforts, so that these eventual commercial efforts will have the evidence that is needed. Some of the most valuable evidence is generated during the clinical trials that support a drug's approval.

CEOCFO: *It takes such a long time for the drug to get approved and to get through the steps. Trends change. How do you take that into account when you decide what companies to work with and how to build a strategy for them?*
Mr. Renick: It is not necessarily a selection by us from a client standpoint. What typically happens with very early molecules is that because the market can change, because it can be such a dynamic marketplace as far as what treatments are favored and how that changes over time—and this is where we have a strong commercial side of the company that supports this—we attempt to examine what a marketplace will look like in three years or five years or 10

years, with all of the known information such as what currently available treatments will be generically available at the time, what else is in the research pipeline, what appear to be the unmet needs both now and over the next decade. Certainly, the entire pharmaceutical industry is always attempting to make sure that they make the right decisions with their early assets, so that they do not go too far with something only to find that there is really not a market for it at the time that it gains approval. There have been some cases of that, just in the past year or so, particularly in a fast-moving therapeutic area like hepatitis C, where in one case a manufacturer was effectively finished with their clinical trials and ready for approval. However, by the time they reached that point, the need for that drug had basically been eliminated, because competitors had developed superior technologies. They ultimately did not launch the drug. That is probably a worst-case scenario. Again, this is something that we can support our clients with—a very thorough evaluation of the marketplace, the various dynamics, and the likely need for a product at the projected time when it would be ready to enter the market.

CEOCFO: ***Do most companies today realize that they need a long-term strategy, or is it still a point of education you need to address for companies to understand they need to look far ahead?***
Mr. Renick: All the clients that we engage with certainly want to look ahead as far as possible. It may depend on the size of the client; some companies are formed with a very specific molecule that will likely be acquired, so their focus may be a little shorter-term. The larger companies that will develop products as well as license or acquire companies that have the right pipeline products will certainly look out longer into the future. Therefore, given the nature of the drug approval process within the US and European markets and around the world, a long-range view is required simply because of the length of time it takes to get a drug approved. Now that said, to my earlier comments, there is an industry-wide attempt to shorten that development timeline by focusing on stratified patient populations and biomarker information such that, even in the early research efforts, you are more highly targeted. You are more likely to move through a trial faster, you attempt to mitigate some of the things that will stretch out a trial and make it more expensive, and so on. As you shorten that, to the question of long-range planning, it tightens your windows somewhat, because you can essentially get to market sooner and not have to deal with the additional risk and the additional unknowns of a much longer R&D timeline.

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CEOCFO: ***When you are working with a company and you are making an assessment at any one of the levels, how do you combine the technology, the statistics, with gut feeling and experience?***
Mr. Renick: You could say it is the value proposition of our company that we are presenting to our clients—the ability to integrate the various things that you just mentioned. We do that through a group of subject matter experts and thought leaders who bring a variety of real-world experiences to the table, because we are very focused on market access and the eventual ability for these drugs to be accessed and reimbursed globally. We bring a number of former payer decision makers within the company to our clients. These range from medical directors to pharmacy directors, quality directors, and others. We also combine that with other thought leaders who are in the market—very highly respected health economists who can help plan for a future situation and all the various economic inputs to be considered, as well as some seasoned pharmaceutical industry veterans who have spent a number of years within pharmaceutical companies and understand the real-world processes within those companies to take a drug candidate into the research environment and ultimately bring it to market and attempt to have it reach appropriate patients.

CEOCFO: ***Do you see additional acquisitions in your company's future?***
Mr. Renick: We are always exploring how we can bring additional capabilities beyond what I just described. That is both in the different capabilities as well as different geographies. Much of our business is currently US-centric; however, we have a fair amount of business that extends beyond the US. We will certainly look to expand that and likely have a more established presence in some key markets around the world, particularly in the European marketplace but also in the AsiaPac community and some other emerging markets around the world. Therefore, geographically we are evaluating opportunities. Then, when we think about other capabilities that our clients will look to further integrate, we'll continue to explore that. We currently have worldwide experience that's growing rapidly as I described, and that includes tremendous analytics capability, health economics capability, and also the ability to support our clients to inform their clinical trial efforts and designs, knowing that those clinical trials and the evidence that is developed within those trials becomes the basis for economic evaluations around the world.

CEOCFO: ***How do you reach out to potential clients? How do they find you?***
Mr. Renick: A key channel is through our network of employees and their network of contacts within the life sciences industry. There are a number of opportunities coming through this avenue because we are well known and we are the

largest company of our type in the US focused on demonstrating and communicating evidence in support of market access and outcomes. Additionally, we receive a number of opportunities in the form of traditional business development driven by extensive marketing activities. Therefore, it is both the incoming work through these channels and the continual opportunity evaluations by our teams, particularly as we see news developing where there is activity in a certain therapeutic area that clearly could benefit from our experience. If there is very early news about a potential medical breakthrough, we will proactively engage with those companies to determine what their needs may be and how we can address their unmet needs. So there is both an active outreach as well as a fairly active incoming pipeline of opportunities.

CEOCFO: ***How have your offerings grown and evolved over time?***
Mr. Renick: The evolution of our offerings has largely followed the evolution of the market. Like any business that wants to stay ahead, you want to look at where the market is going. What we have seen, again very much in the US, is an expansion of stakeholders who are having to bear risk, and this is through the various aspects of the Affordable Care Act as well as just the growth in accountable care in general, both in the commercial and Medicare markets. What this has done is push that risk from traditional risk holders—like health plans that are well known, such as Aetna, Humana, and United—to provider systems, large medical groups, and other stakeholders to the point where nearly every healthcare provider, at this point, bears some kind of risk. In some cases it is a true insurance risk. In other cases it is reimbursement risk that is tied to quality measures or other outcomes measures. As a result, many more stakeholders are asking the question about value. Therefore, our emphasis as a company is to be the leader in generating and communicating the value that is necessary to support the use of a product. Our growth has been largely tied to the fact that more and more participants in the healthcare system are requiring evidence of value, and this goes beyond cost. That is a big change from years past, when physicians were largely self-employed and had very little financial risk when it came to prescribing drugs or ordering tests or procedures. Now, as they more and more are employed versus independent, they are part of a system that is bearing risk, and these systems largely look at their ability to thrive in today's healthcare marketplace. It calls into question why the drug is being utilized, why the test is being ordered, why the device is being implanted, and so on. They all need to have value demonstrated to them. That has been a very nice trend for our company that will continue for a number of years.

CEOCFO: ***What should people reading about Precision for Medicine remember most?***
Mr. Renick: Simply put, our mission is to support our clients in achieving their mission, and collectively the mission of our clients is to improve the healthcare of people around the world. We are very excited to be a part of that. What we know is that in a world of limited resources, but advancing technology, that we are in an unsustainable situation, both from the expense of bringing a drug to market and then the ability to pay for it once it is in the market. So the take on Precision for Medicine is that we align information, science, and technology on behalf of our clients to ensure the most appropriate treatments are delivered in an outcomes-focused, resource-limited world, with the focal point always being on appropriate patients being able to receive and afford the appropriate care.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

Precision for Medicine

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